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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,576	06/13/2001	Clifton A. Alferness	59013-331623	7153

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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10/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/880,576	Applicant(s) ALFERNES ET AL.	
	Examiner Brian Szmal	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,32-34,37 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,32-34,37 and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 June 2001 and 27 February 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/24/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 18, 32-34, 37 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 18 states the jacket is complaint *and elastic* (emphasis added). The current specification clearly states the jacket is inelastic as can be seen in Paragraphs 0061, 0063 and 0071 of the Pre-Grant Publication of this application. Therefore the addition of "elastic" to the claim constitutes new matter.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 18, 32-34, 37 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lederman et al (6,224,540 B1) in view of Jamshidi (5,593,428).

Lederman et al disclose a passive girdle for constraining heart expansion and further disclose accessing the heart (the heart has to be accessed in order to place jacket 30 on the heart); placing a jacket (30) on the heart, the jacket (30) comprising compliant and elastic (as explained in the Applicant's remarks filed on June 9, 2008, regarding the term "elastic"), open cell biocompatible material (33) around the ventricles of the heart to passively constrain circumferential expansion of the heart (See Column 5, lines 35-36); securing the jacket (30) on the heart (See Column 5, lines 52-55); the jacket (30) is secured to the heart using sutures (See Column 5, lines 52-55, attaching the device at 4-6 points along the A-V groove suggests the use of sutures because an adhesive would be incompatible on a beating heart); adjusting the jacket (30) to snugly conform to the external geometry of the heart (See Column 5, lines 55-57); and the jacket (30) is configured to engage a surface of the heart to constrain circumferential expansion of the heart beyond a predetermined maximum volume (See Column 5, lines 26-31, see explanation above).

Lederman et al however fail to disclose causing an electrical element to extend to the heart, to operatively engage the accessed heart to couple electrical therapy to the heart; the electrical elements are pacer leads; the electrical therapy is a defibrillating therapy; and the electrical therapy is a pacing therapy.

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Jamshidi disclose a pacing and defibrillation means for providing therapy to a heart and further disclose causing an electrical element to extend to the heart, to operatively engage the accessed heart to couple electrical therapy to the heart (see Figure 4); the electrical elements are pacer leads; the electrical therapy is a defibrillating therapy; and the electrical therapy is a pacing therapy. See also Column 1, lines 66-67; Column 2, lines 1 and 43-53.

To provide the means of Lederman et al with an electrotherapy means would have been obvious to one of ordinary skill in the art, in view of the teachings of Jamshidi, since all of the claimed elements were known in the prior art and one skill in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention, i.e. one skill in the art would have recognized that the electric therapy as taught by Jamshidi would provide the heart jacket of Lederman et al with an additional means of therapy to a heart already weakened by cardiomyopathy.

Response to Arguments

6. Applicant's arguments filed September 24, 2008 have been fully considered but they are not persuasive.

The Applicants argue the above 112 rejection is improper since the specification incorporates by reference US Pat 5,702,343 in Paragraph 0019 of the publication. The Examiner respectfully disagrees. Paragraph 0019 in the current specification states:

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"Commonly assigned U.S. Pat. No. 5,702,343 to Alferness dated Dec. 30, 1997 teaches a jacket to constrain cardiac expansion during diastole. The present invention pertains to improvements to the invention disclosed in the '343 patent." The current specification does not state US Pat 5,702,343 is "incorporated herein by reference" or "incorporated by reference".

Therefore, the current specification does not provide support for a compliant, elastic material.

7. Applicant's arguments with respect to claims 18, 32-34, 37 and 39-41 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmál whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmál/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736